Notices of Exempt Rulemaking

NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

NOTICE OF EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

[R05-205]

PREAMBLE

1. Sections Affected Rulemaking Action

Exhibit 1 Amend R9-25-509 New Section R9-25-510 Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-136(F), 36-2202(A)(4), and 36-2209(A)(2)

Implementing statutes: A.R.S. §§ 36-2204(8) and 36-2205(A)

Statute or session law authorizing the exemption: A.R.S. § 36-2205(C)

3. The effective date of the rules:

June 8, 2005

4. A list of all previous notices appearing in the Register addressing the exempt rule:

None

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Gene Wikle, Chief

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OR

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6. An explanation of the rule, including the agency's reasons for initiating the rulemaking:

The drug lists in Exhibit 1 to A.A.C. R9-25-503 establish the drugs authorized for administration by different levels of emergency medical technicians (EMTs) and establish the minimum supply level for each drug required to be carried in an ambulance drug box. Effective March 25, 2005, ADHS revised Exhibit 1, according to the recommendations of the Medical Direction Commission (MDC); the Emergency Medical Services (EMS) Council; and the Protocols, Medications, and Devices Committee (PMD), to make the drug lists conform to currently accepted medical standards and industry practices and to make the drug lists clearer and easier to use. At their April 22, 2005, meetings, MDC and EMS Council recommended that ADHS revise the drug lists further to eliminate drug dosage or concentration requirements, leaving only a minimum supply for each drug in the drug lists. ADHS obtained further clarification of these changes at the PMD meeting on May 12, 2005. Consistent with the recommendations of MDC, EMS Council, and PMD, ADHS is amending the drug lists in Exhibit 1 to eliminate virtually all of the drug dosage or concentration requirements. Eliminating these drug dosage or concentration requirements allows EMS providers more flexibility in obtaining drugs from suppliers, which is important when drug shortages occur. Maintaining the minimum supply requirements in the lists ensures that public health is protected because ambulances will be required to carry at least a minimum quantity of each required drug.

Effective April 1, 2005, ADHS adopted A.A.C. R9-25-510, Protocol for EMT-B Carrying and Administration of Aspirin, to clarify that an EMT-Basic (EMT-B) is authorized to carry and administer aspirin for adult patients with chest pain. At their April 22, 2005, meetings, MDC and EMS Council recommended that A.A.C. R9-25-510 be amended to elaborate on the patients to whom an EMT-B is authorized to administer aspirin by stating that an EMT-B can administer aspirin to an adult patient suffering from chest pain or other signs or symptoms suggestive of acute myocardial infarction. Consistent with these recommendations, ADHS is amending A.A.C. R9-25-510 to provide that an EMT-B can administer aspirin to an adult patient suffering from chest pain or other signs or symptoms suggestive of acute myocardial infarction. This change helps to ensure that an adult patient who is suffering from signs or symptoms suggestive of acute myocardial infarction, other than chest pain, is able to receive potentially life-saving aspirin from an EMT-B.

In December 2004, PMD recommended that the EMT-B scope of practice be expanded to allow EMT-Bs to carry and administer epinephrine auto-injectors and made specific recommendations related to how this would be accomplished. In January 2005, MDC and EMS Council also recommended that the EMT-B scope of practice be expanded to allow EMT-Bs to carry and administer epinephrine. In February 2005, ADHS created a draft rulemaking that would add epinephrine auto-injectors to the EMT-B drug list and add a new protocol for EMT-B administration of epinephrine by auto-injector. In March 2005, PMD approved the training requirements included in the draft rulemaking, and ADHS solicited public comment on the draft rulemaking. ADHS received seven sets of comments on the draft rulemaking, almost entirely positive. ADHS presented the draft rulemaking and the comments to MDC and EMS Council at their April 22, 2005, meetings. At those meetings, MDC and EMS Council recommended that ADHS adopt the draft rulemaking. To implement the recommendations of PMD, MDC, and EMS Council, ADHS is adding epinephrine auto-injectors to the EMT-B drug list and adopting a new A.A.C. R9-25-509, Protocol for EMT-B Administration of Epinephrine by Auto-injector. Combined, these changes authorize an EMT-B to carry and administer epinephrine by auto-injector after mandatory training has been completed. To maintain this authorization, an EMT-B is required to complete refresher training at least once every 24 months. Concurrently with this rulemaking, ADHS is adopting as a guidance document a drug profile for epinephrine auto-injectors that ADHS intends to be a tool for the mandatory training. This drug profile has been considered in draft form and revised per the recommendations of PMD, MDC, and EMS Council. At their April 22, 2005, meetings, MDC and EMS Council both recommended adoption of the drug profile, with brand name references eliminated. To be consistent with these recommendations, ADHS has revised the draft rulemaking to eliminate references to brand names that appeared in the draft requirements for mandatory training in A.A.C. R9-25-509(C)(1)(h) and the EMT-B Drug List in Exhibit 1 to A.A.C. R9-25-503. In addition, because there is currently no requirement for a drug box in a Basic Life Support ground ambulance, ADHS has revised the draft reference to the Arizona drug box supply in A.A.C. R9-25-509(C)(1)(h) to acknowledge that the Arizona drug box minimum supply is currently a recommendation. Finally, ADHS made minor technical revisions in A.A.C. R9-25-509(C)(1)(k) and (C)(2) to make the rule more clear, concise, and understandable.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

Not applicable

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10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Not applicable

11. A summary of the comments made regarding the rule and the agency response to them:

Not applicable

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously made as an emergency rule? If so, please indicate the Register citation:

No.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

ARTICLE 5. MEDICAL DIRECTION PROTOCOLS FOR EMERGENCY MEDICAL TECHNICIANS

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Exhibit 1. EMT-P and Qualified EMT-I Drug List; EMT-I Drug List; EMT-B Drug List

R9-25-509. Repealed Protocol for EMT-B Administration of Epinephrine by Auto-injector (A.R.S. §§ 36-2202, 36-2204,

36-2205, and 36-2209)

R9-25-510. Protocol for EMT-B Carrying and Administration of Aspirin (A.R.S. §§ 36-2202, 36-2204, 36-2205, and 36-

2209)

ARTICLE 5. MEDICAL DIRECTION PROTOCOLS FOR EMERGENCY MEDICAL TECHNICIANS

Exhibit 1. EMT-P and Qualified EMT-I Drug List; EMT-I Drug List; EMT-B Drug List

EMT-P AND QUALIFIED EMT-I DRUG LIST

AGENT	AMOUNT & MINIMUM SUPPLY
ADENOSINE	6 or 12 mg dose, minimum of 30 mg
ALBUTEROL SULFATE * (sulfite free)	2.5 mg dose, minimum of 10 mg
AMIODARONE	150 mg dose, minimum of 300 mg
(optional)	
ASPIRIN	81 or 325 mg dose, minimum of 4 doses 324 mg
ATROPINE SULFATE	1 mg dose, minimum of 4 prefilled syringes, total of
	4 mg
	8 mg multidose vial (1), minimum of 8 mg
CALCIUM CHLORIDE	1 g dose, minimum of 1 g
CHARCOAL, ACTIVATED (without sorbitol)	2 g dose, minimum of 50 g
DEXAMETHASONE	4 mg dose, minimum of 8 mg
(optional)	

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DEXTROSE	25 g syringe, minimum of 50 g	
DIAZEPAM	10 mg dose, minimum of 20 mg	
DIAZEPAM RECTAL DELIVERY GEL (optional)	20 mg dose, minimum of 20 mg	
DIPHENHYDRAMINE HCI	50 mg dose, minimum of 50 mg	
DILTIAZEM (optional)	25 mg dose, minimum of 25 mg	
DOPAMINE HCl	400 mg dose, minimum of 400 mg	
EPINEPHRINE HCl, 1:1,000 solution	1 mg dose, minimum of 2 mg 30 mg multidose vial (1), minimum of 30 mg	
EPINEPHRINE HCl, 1:10,000 solution	1 mg dose, minimum of 6 mg	
FUROSEMIDE	20 mg dose, minimum of 100 mg	
or If FUROSEMIDE is not available, BUMETANIDE	0.25 mg dose, minimum of 4 mg	
GLUCAGON	1 mg dose, minimum of 2 mg	
IPRATROPIUM BROMIDE * 0.02%	2.5 mL dose, minimum of 5 mL	
LIDOCAINE HCI IV	100 mg dose, minimum 3 prefilled syringes, total of 300 mg 1 g dose, minimum of 2 g 1 g vials or premixed infusion, total of 2 g	
MAGNESIUM SULFATE	1 g dose, minimum of 5 g	
METHYLPREDNISOLONE SODIUM SUCCINATE	125 mg dose, minimum of 250 mg	
MIDAZOLAM (Versed®) (optional)	5 mg dose, minimum of 10 mg	
MORPHINE SULFATE	10 mg dose, minimum of 20 mg	
NALMEFENE HCI	2 mg dose, minimum of 4 mg	
(optional) NALOXONE HCl	1 mg dose, minimum of 10 mg	
NITROGLYCERIN TABLETS or	0.4 mg dose, minimum of 1 bottle	
NITROGLYCERIN SUBLINGUAL SPRAY	0.4 mg dose, minimum of 1 bottle	
OXYTOCIN (optional)	10 units dose, minimum of 10 units	
PHENYLEPHRINE NASAL SPRAY 0.5%	15 mL bottle, minimum of 1 bottle	
SODIUM BICARBONATE 8.4%	50 mEq dose, minimum of 100 mEq	
THIAMINE HCI	100 mg dose, minimum of 100 mg	
VASOPRESSIN (optional)	40 units dose, minimum of 40 units	
VERAPAMIL HCI	5 mg dose, minimum of 10 mg	

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NITROUS OXIDE (optional)	Nitrous oxide 50% / Oxygen 50% fixed ratio setup with O ₂ fail-safe device and self-administration mask, minimum of 1 setup
SYRINGES	1 mL tuberculin , minimum of (2) 3 mL , minimum of (4) 10-12 mL , minimum of (4) 20 mL , minimum of (2) 50-60 mL , minimum of (2)
FILTER NEEDLES	5 micron , minimum of (3)
NON-FILTER NEEDLES	assorted sizes
INTRAVENOUS SOLUTIONS:	
(Bulk restricts inclusion of all fluids in drug box)	
DEXTROSE, 5% in water	250 mL bag , minimum of (1)
LACTATED RINGER'S	1 L bag , minimum of (4)
NORMAL SALINE	1 L bag , minimum of (4) 250 mL bag , minimum of (3) 50 mL bag , minimum of (2)

* Administer by nebulizer

Note: No change

EMT-I DRUG LIST

AGENT	AMOUNT & MINIMUM SUPPLY
ALBUTEROL SULFATE * (sulfite free)	2.5 mg dose, minimum of 10 mg
ASPIRIN	81 or 325 mg dose, minimum of 4 doses 324 mg
ATROPINE SULFATE	8 mg multidose, minimum of 8 mg multidose vial (1)
CHARCOAL, ACTIVATED (without sorbitol)	2 g dose, minimum of 50 g
DEXTROSE	25 g syringe, minimum of 50 g
DIAZEPAM	10 mg dose, minimum of 20 mg
DIAZEPAM RECTAL DELIVERY GEL (optional)	20 mg dose, minimum of 20 mg
DIPHENHYDRAMINE HCI	50 mg dose, minimum of 50 mg
EPINEPHRINE HC1, 1:1,000 solution	1 mg dose, minimum of 2 mg
EPINEPHRINE HCl, 1:10,000 solution	1 mg dose, minimum of 6 mg

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FUROSEMIDE	20 mg dose, minimum of 100 mg	
or	20 mg 4000, mmmam 01 100 mg	
If FUROSEMIDE is not available,		
BUMETANIDE	0.25 mg dose, minimum of 4 mg	
GLUCAGON	1 mg dose, minimum of 2 mg	
IPRATROPIUM BROMIDE * 0.02%	2.5 mL dose, minimum of 5 mL	
IPRATROPIUM BROMIDE * 0.02%	2.5 mL dose, minimum of 5 mL	
METHYLPREDNISOLONE SODIUM SUCCINATE	125 mg dose, minimum of 250 mg	
MIDAZOLAM (Versed®)	5 mg dose, minimum of 10 mg	
(optional)		
MORPHINE SULFATE	10 mg dose, minimum of 20 mg	
NALMEFENE HCl	2 mg dose, minimum of 4 mg	
(optional)		
NALOXONE HCl	1 mg dose, minimum of 10 mg	
NITROGLYCERIN TABLETS	0.4 mg dose, minimum of 1 bottle	
or	0.4 mg dose, minimum or 1 bottle	
NITROGLYCERIN SUBLINGUAL SPRAY	0.4 mg dose, minimum of 1 bottle	
OXYTOCIN	10 units dose, minimum of 10 units	
(optional)		
PHENYLEPHRINE NASAL SPRAY 0.5%	15 mL bottle, minimum of 1 bottle	
SODIUM BICARBONATE 8.4%	50 mEq dose, minimum of 100 mEq	
THIAMINE HCI	100 mg dose, minimum of 100 mg	
NITROUS OXIDE		
(optional)	Nitrous oxide 50% / Oxygen 50% fixed ratio setup with O ₂ fail-safe device and self-administration	
(optional)	mask, minimum of 1 setup	
SYRINGES	1 mL tuberculin , minimum of (2)	
STRINGES	3 mL , minimum of (4)	
	10-12 mL , minimum of (4)	
	20 mL , minimum of (2)	
	50-60 mL , minimum of (2)	
FILTER NEEDLES	5 micron , minimum of (3)	
NON-FILTER NEEDLES	assorted sizes	
INTRAVENOUS SOLUTIONS:		
(Bulk restricts inclusion of all fluids in drug box)		
DEXTROSE, 5% in water	250 mL bag , minimum of (1)	
LACTATED RINGER'S	1 L bag , minimum of (4)	
NORMAL SALINE	1 L bag , minimum of (4)	
	250 mL bag , minimum of (3)	

^{*} Administer by nebulizer

Note: No change

Notices of Exempt Rulemaking

EMT-B DRUG LIST

AGENT	AMOUNT & MINIMUM SUPPLY
ASPIRIN	81 or 325 mg dose, minimum of 4 doses 324 mg
EPINEPHRINE AUTO-INJECTOR	2 adult auto-injectors 2 pediatric auto-injectors

R9-25-509. Repealed Protocol for EMT-B Administration of Epinephrine by Auto-injector (A.R.S. §§ 36-2202, 36-2204, 36-2205, and 36-2209)

- A. For an EMT-B, the ability to administer epinephrine by auto-injector is an optional skill attained by completing training for the administration of epinephrine by auto-injector as prescribed in this Section.
- **B.** The administration of epinephrine by auto-injector is not an advanced procedure that requires an EMT-B to have administrative medical direction and on-line medical direction.
- C. An EMT-B shall not administer epinephrine by auto-injector until the EMT-B has completed training that:
 - <u>Includes at least two clock hours covering:</u>
 - a. The requirements of this Section;
 - b. The epidemiology and physiology of anaphylaxis and allergic reaction;
 - The common methods of entry of substances into the body;
 - d. The common antigens most frequently associated with anaphylaxis;
 - The physical examination of patients with complaints associated with anaphylaxis or allergic reaction;
 - The signs and symptoms of anaphylaxis, allergic reaction, and respiratory distress associated with anaphylaxis;
 - g. Differentiating between anaphylaxis and other medical conditions that may mimic anaphylaxis;
 - The following information about epinephrine by auto-injector:
 - Class,
 - ii. Mechanism of action,
 - iii. Indications and field use,
 - iv. Contraindications,
 - v. Adverse reactions,
 - vi. Incompatibilities and drug interactions,
 - vii. Adult dosage,
 - viii. Pediatric dosage,
 - ix. Route of administration,
 - x. Onset of action, xi. Peak effects,

 - xii. Duration of action,
 - xiii. Dosage forms and packaging,
 - xiv. Recommended Arizona drug box minimum supply, and
 - xv. Special considerations;
 - The proper storage of an epinephrine auto-injector;
 - i. Medical asepsis;
 - k. The use of standard precautions, as defined in A.A.C. R9-6-101, and body substance isolation procedures when administering a medication by injection;
 - The proper disposal of contaminated objects and sharps; and
 - m. Documenting the administration of epinephrine by auto-injector;
 - 2. Includes pre-training and post-training written evaluations and a practical skills evaluation to ensure that the EMT-B demonstrates competency in the subject matter listed in subsection (C)(1); and
 - Is approved by the EMT-B's administrative medical director or, if the EMT-B does not have an administrative medical director, by the emergency medical services provider for which the EMT-B works.
- **<u>D.</u>** An EMT-B who has completed initial training as described in subsection (C) and who desires to maintain authorization to administer epinephrine by auto-injector shall complete refresher training that complies with subsection (C) at least once every 24 months after completing the initial training.

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R9-25-510. Protocol for EMT-B Carrying and Administration of Aspirin (A.R.S. §§ 36-2202, 36-2204, 36-2205, and 36-2209)

- A. An EMT-B is authorized to carry aspirin for administration as described in subsection (B).
- **B.** An EMT-B is authorized to administer aspirin only to an adult patient who is suffering from chest pain or other signs or symptoms suggestive of acute myocardial infarction.
- C. An EMT-B's administration of aspirin to an adult patient who is suffering from chest pain or other signs or symptoms suggestive of acute myocardial infarction is not an advanced procedure that requires the EMT-B to have administrative medical direction and on-line medical direction.
- **D.** For purposes of this Section, "adult" means 18 years of age or older.